



Medicines and Healthcare products
Regulatory Agency

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To interested parties

January 2005

MLX 318: CONSULTATION ON PROPOSED HERBAL MEDICINES ADVISORY COMMITTEE

I am writing to interested parties to invite comments on updated proposals for a new Herbal Medicines Advisory Committee. The Agency first consulted on the possibility of establishing an advisory body on herbal medicines in February 2004 (MLX 300 – available on the Agency’s website). In view of the fact that the MHRA has revised the proposals in the light of responses to that consultation we are consulting again on the proposals.

This consultation is designed to meet the Government’s Code of Practice on written consultation which states that the Government will:

- Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy.
- Be clear about what the proposals are, who may be affected, what questions are being asked and the timescale for responses.
- Ensure that the consultation is clear, concise and widely accessible.
- Give feedback regarding the responses received and how the consultation process influenced the policy.
- Monitor the department’s effectiveness at consultation, including through the use of a designated consultation co-ordinator.
- Ensure consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment (RIA) if appropriate.

In this instance we do not consider there is a need to carry out a RIA.

Responding to the Consultation

Please send your comments on these proposals by **22 April 2005** to:

Judith Thompson
16-161
Herbal Policy Unit
MHRA
Market Towers Room
1 Nine Elms Lane
London SW8 5NQ

You may also e-mail your response to:
judith.m.thompson@mhra.gsi.gov.uk

Publication of comments

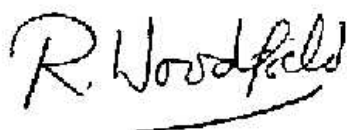
To help informed debate on the issues raised by this consultation exercise, the Agency intends to make publicly available responses received to this consultation. Copies will be available shortly after the public consultation has concluded.

The Agency's Information Centre at Market Towers will supply additional copies of the results of the consultation on request. Copies may be further reproduced. An administrative charge, to cover the cost of photocopying and postage, may be applied.

We will assume that your comments can be made publicly available in this way unless you indicate on the pro forma at Annex A that you wish all or part of them to be treated as confidential and excluded from this arrangement.

Should you have any questions regarding the proposals or the conduct of the consultation exercise, please contact Judith Thompson (contact details above). Further paper copies of this letter and with attachments are available on request. If you consider there are other organisations that should be invited to comment on these proposals, please either pass a copy of the documents to them or contact the MHRA and we will arrange for a consultation pack to be sent to them.

Yours faithfully

A handwritten signature in black ink that reads "R. Woodfield". The signature is written in a cursive style with a horizontal line underneath the name.

Richard Woodfield
Herbal Policy Group Manager

CONSULTATION ON PROPOSED HERBAL MEDICINES ADVISORY COMMITTEE

Summary

1. This consultation invites comments on updated proposals for the creation of a new advisory committee on herbal medicines. It is proposed that the Herbal Medicines Advisory Committee should be established as a Section 4 committee under the Medicines Act 1968. This Committee would advise Ministers directly on areas for which the Committee is responsible. It is proposed that the Committee's remit would be the registration scheme to be introduced under the Directive on Traditional Herbal Medicinal Products and unlicensed herbal medicines. We envisage that membership of the Committee would, collectively, encompass: knowledge of the main herbal traditions present in the UK; a wide range of relevant scientific expertise; the practice of healthcare; and lay membership.

Background

2. Consultation letter MLX 300, issued in February 2004, set out proposals for restructuring the advisory bodies set up under the Medicines Act 1968. One element of the proposals was that a specific advisory group for herbal medicines should be created. This group, like the other proposed therapeutic advisory groups, would submit its advice to the proposed new Commission that would be formed by amalgamating the functions of the present Medicines Commission and the Committee on the Safety of Medicines for human use.
3. In November 2004 MHRA issued consultation letter MLX 316 about a review of the code of practice on interests to apply to the Chairman and members of the advisory bodies laid down in the Medicines Act 1968. This consultation confirmed that Ministers had decided to proceed broadly in line with the earlier proposals for restructuring.
4. MLX 316 summarised the proposed new structure as comprising the following:
 - A new Commission that amalgamates the responsibilities of the present Medicines Commission and the Committee on Safety of Medicines and will advise Ministers direct on matters relating to medicines for human use;
 - A number of committees established by Ministers by Orders made under Section 4 of the Medicines Act 1968 (Section 4 committees) which will advise the Ministers direct on issues for which they are responsible;
 - Sub-committees called expert advisory groups (EAGs) which will advise the section 4 committees and the new Commission;
 - A list of experts on whom the Commission and the other committees and groups can call for advice;

- Lay/patient representatives on each of the committees and sub-committees.
5. Ministers have decided that in relation to herbal medicines they wish to amend the proposals as originally set out in MLX 300. As this change is significant the MHRA considers it would be helpful to hold a further consultation to allow interested parties an opportunity to comment on the detail of the revised proposal.

Proposals for a Herbal Medicines Advisory Committee

6. We propose that there should be established a new Herbal Medicines Advisory Committee (HMAC). This Committee will be set up by Order under Section 4 of the Medicines Act 1968. It will give advice directly to Ministers and the MHRA (rather than advising via the new Commission as would have been the case under the original proposals).
7. In a comparable move Ministers have announced that the Advisory Board on the Registration of Homoeopathic Products will remain as a Section 4 committee.
8. The revised proposals for herbal medicines:
- are consistent with the new European advisory committee structure based at the European Medicines Agency where there is now a free-standing Herbal Medicinal Products Committee alongside the Committee on Human Medicinal Products;
 - reflect the growing interest in herbal medicines both on the part of the consumer and the scientific community and the importance the Government attaches to reformed regulation of herbal medicines, in particular the Directive on Traditional Herbal Medicinal Products (Directive 2004/24/EC);
 - reflect further thinking within the Agency on how consistency in scientific and regulatory advice could be promoted where free-standing advisory committees are operating in areas of common interest;
 - respond positively to arguments advanced by respondents in the herbal sector during consultation on MLX 300.

Proposed remit of the Herbal Medicines Advisory Committee

9. We propose that the remit of the HMAC should cover advice on matters relating to:
- the regulation of products under the Directive on Traditional Herbal Medicinal Products;
 - the regulation of unlicensed herbal medicines.
10. We propose that responsibility for giving advice on herbal medicines in relation to marketing authorisations should be for the new Commission. This is because the key issue with marketing authorisations is the assessment of

whether the evidence of benefit of the product outweighs the risk. In such situations the issue of whether a product contains herbal ingredients is of relatively lesser significance compared with the importance of applying consistent standards of risk/benefit analysis across all medicines.

11. With regard to registration of herbal medicinal products under the Directive on Traditional Herbal Medicinal Products HMAc will be responsible for advising on quality, safety and traditional use. HMAc would also be responsible for advising on the legal status of registered products, in particular whether products should be General Sale List or Pharmacy status.
12. Advice on unlicensed herbal medicines will cover medicines placed on the market under Section 12 of the Medicines Act 1968:
 - manufactured unlicensed herbal medicines on the UK market at April 2004 that are covered by transitional protection for a period before they are required to comply with the Directive on Traditional Herbal Medicinal Products;
 - unlicensed herbal medicines made up by, or at the request of, practitioners for use in one to one consultations. Consultation letter MLX 299 put forward outline proposals for reform of this regime and, in the event that these reforms are pursued, HMAc would be the appropriate advisory Committee to be consulted.
13. HMAc will also be the appropriate Committee in the event that there is a need for advice in relation to possible prohibitions of particular herbal ingredients under Section 62 of the Medicines Act 1968 in unlicensed products. Likewise, it would fall to HMAc to advise on updating of the list of restricted herbal ingredients used in unlicensed medicinal products (currently listed in the Schedules to the Medicines (Retail Sale or Supply of Herbal Remedies) Order 1977 (SI 1977/2130).
14. The proposed terms of reference of HMAc will be to give advice to Ministers on the safety, quality and traditional use of registered and unlicensed herbal medicines, and in particular on:
 - products that will be registered under the Traditional Herbal Medicines Registration Scheme (THMRS) to be introduced in October 2005 to implement the Directive on Traditional Herbal Medicinal Products (2004/24/EC);
 - registration applications that the licensing authority is minded to refuse;
 - representations made (either in writing or at a hearing) by an applicant or a registration holder where the licensing authority is minded to refuse, suspend, revoke or vary a registration;
 - the registration of other types of traditional medicines should the scope of Directive 2004/24/EC be extended in due course to cover such products;
 - unlicensed manufactured herbal medicines during the transitional period;

- unlicensed herbal medicines made up to meet the needs of individual patients (Section 12(1) of the Medicines Act 1968) and associated regulatory reforms, including a review of the herbal ingredients currently restricted or prohibited in medicines (SI 2130/1977) and any extensions to the scope of the Section 12(1) regime.

Right to make representations

15. We propose that there should be a right to make representations to HMAc in relation to products registered in accordance with the Directive on Traditional Herbal Medicinal Products. The arrangements would apply by analogy with what was proposed for marketing authorisations in paragraphs 41 and 42 of MLX 300.
16. We propose that the following procedure would apply to applications under the traditional use registration scheme: in outline, the licensing authority will refer any applications that it is minded to refuse to HMAc. Applicants would then have a right to make representations in writing or to have a hearing together with the opportunity to make written representations to HMAc if HMAc's provisional view were adverse. The HMAc would consider the representations then give its final view to the licensing authority, which would make its decision. If the decision of the licensing authority were adverse, the applicant would be given the opportunity of appealing to a "person appointed" by the licensing authority. The same procedure would apply to proposals by the licensing authority to suspend or revoke a traditional use product registration.
17. In line with existing arrangements, applications and proposals for the suspension, revocation and variation of manufacturers' and wholesale dealers' licences would be subject only to the "person's appointed" procedure.

Membership

18. We propose that HMAc would consist of a minimum of 8 members, plus chairman. In practice we envisage that membership will consist of up to 16 members, depending on the numbers needed to encompass the areas of skill and experience identified as necessary.
19. We propose that the Committee Members should be recognised by their peers as an eminent member of their profession and have wide and recent experience in a wide range of specialities and have shown expertise in one of the following areas:
 - Practise of herbalism (Western tradition)
 - Practise of herbalism (Chinese tradition)
 - Practise of herbalism (Ayurveda tradition)
 - General practice (medicine)
 - Toxicology
 - Pharmacy including pharmaceutical quality and standards

- Pharmacognosy
- Clinical pharmacology
- Paediatrics
- Hospital physician (academic or consultant)
- Clinical epidemiology
- Pharmacovigilance

20. In addition there would be two lay members.

21. In line with existing arrangements for advisory bodies, the Agency will maintain a list of experts who could be called on to give advice to HMAc as needed, for example if an existing member of HMAc was unable to attend. There might also be occasions when the HMAc needed to supplement its expertise in relation to another herbal tradition.

Co-ordination and consistency of advice

22. The new Commission and Section 4 committees will be supported by a number of sub-committees called Expert Advisory Groups (EAGs). The EAGs will be able to provide advice to the Commission and Section 4 committees as appropriate. EAGs likely to be of particular importance to the work of HMAc will include ones on Pharmacovigilance and on Pharmacy and Standards.

23. In their specialist areas of expertise EAGs will play an important role in facilitating a consistent approach between the Commission and Section 4 committees. For example, if there was an emerging safety issue relating to a specific herbal ingredient this might potentially affect herbal medicines with a marketing authorisation, as well as registered herbal medicines and unlicensed herbal medicines made up by herbalists. Expert assessment of the issue and advice from the Pharmacovigilance EAG to both the new Commission and to HMAc should facilitate the latter two advisory bodies giving consistent advice in relation to the various herbal medicines which come within their respective remits. In addition, in such a situation the Chairman and one or more member of the EAG could attend relevant meetings of the new Commission and HMAc in order to discuss and explain their advice.

Interests

24. MLX 316 set out proposals for tightening rules on interests. In the light of the current proposal that HMAc should be constituted as a Section 4 committee, the relevant provisions as set out in MLX 316 would be those that apply to the chairman and members of Section 4 committees. A key element of the proposals, applicable to HMAc therefore, is that the chairman and members of section 4 committees should not hold current personal interests in the pharmaceutical industry. By analogy, it is proposed that the chairman and members of HMAc should not hold current personal interests in any parts of the herbal industry whose business may be considered relevant to their work on the advisory body. This would include interests in parts of the herbal

industry, such as the food supplements industry, that might not be regarded as being “pharmaceutical”.

Conclusion

25. The MHRA would be grateful for any views, comments and suggestions on the proposals outlined above. We would particularly welcome your views on:

- The name of new Committee;
- Its terms of reference;
- Its size and composition, with particular reference to the competencies and experience necessary to ensure the committee can fulfil its role.

26. A proforma is attached for replies. These may be made by post or e mail and should reach the MHRA **by 22 April 2005**.

RESPONSE TO CONSULTATION LETTER MLX 318

PROPOSAL TO ESTABLISH A HERBAL MEDICINES ADVISORY COMMITTEE

Please complete the proforma and return it to Judith Thompson, Room 16-161 MHRA, Market Towers, 1 Nine Elms Lane, London SW8 5NQ or e-mail it to judith.m.thompson@mhra.gsi.gov.uk

Name:.....

Company name (if applicable).....

Confidentiality Declaration

Please note that it will be assumed that your reply can be made publicly available unless you indicate that you wish all or part of it to be treated as confidential and excluded from this arrangement.

- *1. We do not propose to comment on the proposals in MLX 318
- *2. Our comments on the proposals in MLX 318 are below/overleaf/attached

*Our reply may be made freely available

*Our reply is confidential

*Our reply is partially confidential (indicate clearly in the text of the reply the material to be regarded as confidential)

*Delete as appropriate

I(we) have the following comments to make on the proposals:

(Please use additional sheets as required)

ANNEX B – distribution list

ABPI
Acne Support Group
Advanced Life Support Group
Advertising Association
Advertising Standards Authority
Advisory Committee on Misuse of Drugs
Age Concern London
Ainsworths
Allergan Ltd
Alliance for Natural Health
Andean Medicine Centre Ltd
Anthroposophical Medical Association
Aqueous II (NHS Information Authority)
Arthritis Care
Arthritis Research Campaign
Assn of Respiratory Nurse Specialist
Assoc of Anaesthetists of GB and Ireland
Assoc of British Cardiac Nurses
Assoc of British Dispensing Opticians
Assoc of British Health Care Industries
Assoc of Clinical Res in the Pharm Industry
Assoc of Clinical Research Contractors
Assoc of Community Health
Assoc of Contacts Lens Manufacturers
Assoc of Ind. Clin. Research Contractors
Assoc of Independent Multiple Pharmacies
Assoc of Medical Research Charities
Assoc of Palliative Medicine
Assoc of Traditional Chinese Medicine UK
Association for Nurse Prescribing
Association for Residential Care
Association for Sick Children
Association of Hospice Management
Association of Optometrists
Association of Pharmaceutical Importers
Association of Scottish Trusts CP(ASTCP)
Association of Surgeons of GB & Ireland
Association of Traditional Chinese Medicine
UK
Association of Veterinarians in Industry
Asthma & Allergy Research
ATC
Aventis Pharma Ltd
Ayurveda UK Foundation
Ayurvedic Medical Association UK
Ayurvedic Trade Association
BAAAP
BBSRC
Besselaar Clinical Research Unit
BHMA
Bio-Health Ltd
Bioindustry Association
Birth Control Trust
BMA (Wales)
BMA Scottish Branch
Bristol-Myers Squibb
Bristol-Myers Squibb
Brit Assoc for Nutritional Therapists
Brit Assoc of European Distributors
Brit Assoc of European Pharm Distributor
Brit Assoc of Pharmaceutical Physicians
Brit Assoc of Pharmaceutical Wholesalers
Brit Assoc of Research Quality Assurance
Brit Cardiac Patients Association
Brit Oncological Association
British Acupuncture Council
British Assoc of Chemical Specialities
British Assoc of Dermatologists
British Assoc of European Distributors
British Association of Nutritional Therapies,
British Complementary Medicines Association
British Contact Dermatitis Group
British Dental Association
British Dental Association (N Ireland)
British Dental Association (Scotland)
British Dental Association (Wales)
British Diabetic Association
British Dietetic Association
British Epilepsy Association
British Generic Manufacturers Association
British Heart Foundation
British Herb Trade Association
British Herbal Medicines Association
British Homeopathic Association
British Institute Of Regulatory Affairs
British Medical Association
British Medical Association (N Ireland)
British Osteopathic Association
British Pharmacological Society
British Pregnancy Advisory Service
British Retail Consortium
British Retail Consortium
British Society for Allergy
British Society for Allergy & Clinical
Immunology
British Society for Allergy, Environmental and
Nutritional Medicine
British Standards Institute
British Toxicology Society
CAMedica
Cancer Research Campaign
Cancer Research UK
CARE
CCCPH
CEMVO
Central Medical Advisory Committee
Cephalon UK Ltd
Chemist & Druggist
Chinese Competent Authority
Chinese Medical Institute & Register
CMAS
College Of Pharmacy Practice
Commission For Racial Equality
Common Services Agency
Common Services Agency
Commonwealth Working Group On
Traditional & Complementary Health
Community Pharmacy Magazine

Community Pharmacy Wales
 Company Chemist Association Ltd
 Consumers Association
 Consumers For Health Choice
 Consumers In Europe Group
 Council For Comp & Alternative Medicine
 Council For Responsible Nutrition
 Councils Of Heads Of Medical Schools
 CPHVA
 CTPA Ltd
 CWS Ltd
 DEFRA - Global Wildlife Division
 Department Of Health & Social Services NI
 Diabetes UK
 Dispensing Doctors Association
 Doctor Magazine
 Dr China
 Drug & Therapeutics Bulletin
 Drug Information Pharmacists Group
 DTI
 Earthforce Ltd
 East West Natural Products
 EISAI Ltd
 English National Board for Nursing
 EPSRC
 ESCOP Secretariat
 Essential Oil Trade Association
 European Assn Hospital Pharmacists
 European Council For Classical Homeopath
 European Herbal Practitioners Association
 Faculty Of Homeopathy
 Faculty Of Pharmaceutical Medicine
 FDC Reports
 Food & Drink Association
 Food Commission UK Ltd
 Foundation For Integrated Medicine
 Foundation for Intergrated Health
 FSID
 General Dental Council
 General Medical Council
 General Practitioners Association (NI)
 General Practitioners Committee
 General Practitioners Committee (Wales)
 Glaxosmithkline
 GNC
 Guild Of Healthcare Pharmacists
 HCSA
 Health & Safety Executive
 Health Development Agency
 Health Food Business Magazine
 Health Food Manufacturer's Association
 Health Professions Council
 Health Promotion England
 Health Service Commissioner
 Health Which
 Heathfield Family Centre
 HFMA
 Hoechst Marion Roussel
 Holland & Barrett
 ICON Regulatory Division
 IFA
 IHRC
 Independent Healthcare Association
 Institute for optimum nutrition,
 Institute Of Health Food Retailing
 Int Society For Pharmaco-Epidemiology
 Internal Holistic Aromatherapy
 International Prof Aromatherapists
 Intl Society Of Pharmacovigilance
 Intl. Federation of aromatherapists
 Kings College Hospital
 LACOTS - Co-Ordinating Body on Food and
 Trading Standards
 LIFE
 Long Term Medical Conditions Alliance
 Maharishi Ayurveda Products
 Margaret Anderson AND Associates
 Medical Protection Society
 Medical Protection Society Ltd
 Medical Research Council
 Medical Toxicology Unit
 Medical Womens Federation
 Medicines Monitoring Unit
 Menarini Pharmaceuticals UK Ltd
 MIMMS
 Mind
 National Aids Trust
 National Assembly for Wales
 National Assoc of Women Pharmacists
 National Association of GP Co-Operatives
 National Association of Health Stores
 National Asthma Campaign
 National Board for Nursing, Midwifery &
 Health Visting for NI
 National Consumer Council
 National Council for Hospices and Specialist
 Palliative Care Services
 National Eczema Society
 National Institute of Medical Herbalists
 National Patient Safety Agency
 National Pharmaceutical Association
 Natropathic Forum (UK)
 Natural Medicines Manufacturers' Asn UK
 Natural Medicines Society
 NCH & SPCS
 Nelsonbach
 Neurological Alliance
 NHS Alliance
 NHS Confederation
 NHS Information Authority
 NHS Pharmaceutical Quality Control Comm.
 NMMA
 Northern Ireland Consumer Council
 Novartis Consumer Health
 Nursing & Midwifery Council
 Only Natural Products
 OTC Bulletin
 OTC Business News
 OTC News & Market Report
 Paediatric Chief Pharmacists Group

Pain Society (The)
 Pan European Federation of TCM Societies
 Patients Association
 Pavilion Healthcare International Ltd
 PECMI
 Peninsula Medical School
 Peter Black Healthcare Ltd
 Pfizer Consumer Healthcare
 Pharmaceutical Journal
 Pharmaceutical Quality Group
 Pharmaceutical Society for NI
 Pharmacia Ltd
 Pharmacy Insurance Agency
 Pharmag
 PI Pharma
 Postlethwaite's Herbal Products
 Potters (Herbal Supplies) Ltd.
 Primary Care Pharmacists Assoc.
 Proprietary Association of Great Britain
 Public Health Laboratory Service Board
 Quality Improvement Scotland (NHS)
 Queens University
 Reckitt Benckiser
 Register for Chinese Herbal Medicine
 Rethink
 Royal Botanic Gardens, Kew
 Royal Col. of Paediatrics & Child Health
 Royal College of Anaesthetists
 Royal College of General Practitioners
 Royal College of General Practitioners
 Royal College of Midwives
 Royal College of Nursing
 Royal College of Nursing (NI)
 Royal College of Nursing (Wales)
 Royal College of Nursing Scotland
 Royal College of Obstet & Gynaecologists
 Royal College of Ophthalmologists
 Royal College of Paediatrics & Child Health
 Royal College of Pathologists
 Royal College of Physicians
 Royal College of Physicians & Surgeons
 Royal College of Physicians (Edinburgh)
 Royal College of Physicians (London)
 Royal College of Psychiatrists
 Royal College of Radiologists
 Royal College of Surgeons
 Royal College of Surgeons (Edinburgh)
 Royal Pharm Society of GB (Scotland)
 Royal Pharm Society of GB (Wales)
 Royal Pharmaceutical Society of GB
 Royal Society for the Promotion of Health
 Royal Society of Chemistry
 RPSGB (Scotland)
 RPSGB Welsh Executive
 Scottish Association of Health Councils
 Scottish Consumer Council
 Scottish Deans Medical Curriculum Group
 Scottish Executive Department of Health
 Scottish General Medical Services Comm.
 Scottish General Practitioners Committee
 Scottish Pharmaceutical Federation
 Scottish Pharmaceutical General Council
 Scottish Wholesale Druggists Association
 SCRIP
 Shadow Nursing & Midwifery Council
 Skin Care Campaign
 Small Business Service
 Smithkline Beecham Plc
 Society for Prom of Nutritional Therapy
 Society of Homeopaths
 Society of Pharmaceutical Medicine
 Solgar Vitamins Ltd.
 Suffolk Port Health Authority,
 SWITCH
 TAPASI
 The British Association of Flower Essence
 Producers
 The British Flower and Vibrational Essences
 Association
 The British Medical Journal
 The British Society for Allergy
 The British Thoracic Society
 The Herb Society
 The Institute for Complementary Medicine
 The Lancet Publishing Group
 The Organic Herb Trading Company
 Tic-Tac Administration
 Traditional Herbal Medicinal Producers
 Tutssels Enterprise IG
 UK Clinical Pharmacy Assn
 UK Homoeopathic Medical Association
 UK Inter-Professional Group
 Ulster Chemist Review
 Unified Register of Herbal Practitioners
 Veterinary Medicines Directorate (VMD)
 Viatris Pharmaceuticals Ltd
 Volunteer Development Scotland
 Welsh Consumer Council
 Welsh National Board for Nursing